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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,711	03/04/2002	Patricia Rockwell	11245/46212	5402

7590

01/29/2004

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One Broadway
New York, NY 10004

EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,711

Applicant(s)

ROCKWELL ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 1-32 and 34-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3&6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1-52 are pending.

Election/Restrictions

1. Applicant's election without traverse of group V, claims 29 and 33 in Paper No. 6 is acknowledged.
2. Because applicant did not distinctly and specifically point out any errors in the restriction requirement, the election is Final.
3. Claims 1-28, 30-32 and 34-52 are withdrawn from the consideration. Claims 29 and 33 are pending.

Specification

4. The disclosure is objected to because of the following informalities:
 - a. The reference of WO 93/2319 appeared on the PTO-1449 filed on 10/27/2003 should be WO 93/21319.
 - b. The publication date of reference by Millauer et al. listed in the PTO-1449 filed on 10/27/2003 should not be "a993".An appropriate correction is required.

Priority

5. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 112 as follows:
6. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).
7. In the instant case, claim 29 and 33 are not disclosed in the parental Applications Serial Number 08/967, 113 filed on November 10, 1997, Serial Number 08/476,533 filed June 7, 1995,

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Serial Number 08/326,552, filed on October 20, 1994, and Serial Number 08/196,041 fled February 10, 1994. Therefore, the domestic priority of claims 29 and 33 applied for the earlier filling date of parental application is denied.

8. This application repeats a substantial portion of prior Application No. 08/967,113, filed November 10, 1999, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Claims Rejection - under 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 29 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was **a new matter** that was not described in any parental applications as the current application applied for as a continuation. This is also **a written description rejections under 35 USC § 112 because** claims 29 and 33 are also not described in current the Application in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. Claim 29 is directed to a process of preparing a polypeptide by using a cell lines that expresses a nucleic acid molecule encoding the variable region of a monoclonal antibody that specifically binds to an extracellular domain of a flt-1 receptor and neutralizing activation of the receptor followed by isolation of the polypeptide from the cultured cells.

12. Claim 33 is directed to a process of preparing a polypeptide by using a cell line that expresses a nucleic acid molecule encoding the variable region of a monoclonal antibody that

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specifically binds to an extracellular domain of a flt-1 receptor and inhibit a tumor growth in a mammal followed by isolation of the polypeptide from the cultured cells.

13. It has been noticed that the specification teaches that administration of a monoclonal against VEGF receptor can bind the intracellular domain of VEGF receptor, which result in the inhibition of VEGF receptor phosphorylation or reducing growth cell proliferation in response to the treatment of VEGF. The specification also demonstrate that monoclonal antibody DC101 can block the growth of VEGF-expressing tumor cells and disrupt ongoing angiogenesis leading to inhibition of tumor invasion in animal model. Nevertheless, all of the working examples taught by specification are direct to use a monoclonal antibody against VEGF. None of example is drawn to use a process for preparing a polypeptide or isolating a polypeptide by culturing a cell that expresses a nucleic acid molecule that encodes an amino acid sequence of a variable region of a monoclonal antibody against a VEGF receptor flt-1 by assessing a phenomena of the inactivation of flt-1 receptor or assessing the inhibition of a tumor growth in vitro or in vivo.

14. Applicants are recommended to See the case law of *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997): The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention.... and at page 1406: a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

15. See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021: A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

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16. The case law of *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016, which teach that the disclosure of a process for obtaining cDNA and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

17. In the instant case, while the claimed invention is directed to a method for isolating a polypeptide encoding the variable region of a monoclonal antibody against VEGF. Although the technique is so obvious to the method of making single chain antibody etc. that can be found in the field, the specification does not have any description of claimed method. 35 USC 112 still requires inter alia that “a patent specification contain a written description of the invention and the manner and process of making and using it in such full clear and concise terms as to enable one skilled in the art to make and use the invention. Especially, the specification of current application or any parental application does not describe which monoclonal antibody is used and which DNA library encoding the variable region of a monoclonal antibody against VEGF is used for claims 29 and 33. Moreover, each and every step of claimed methods in claims 29 and 33 are not described at all in any of the applications mentioned above. Therefore, the claims 29 and 33 are new matter introduced into the current Application since it is claimed as a continuation of parental application 08/967,113. In addition, the claims are also rejected under 112, 1st paragraph of written description because the Application as filed does not have the possession of claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

January 10, 2004


JAMES HOUSEL 12/4/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600